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Jane Henney, M.D
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Room 1471
Rockville, MD 20857

Dear Dr. Henney:

In 1977, the Food and Drug Administration (FDA) initiated proceedings to ban the sub- therapeutic uses of penicillin and tetracyclines in animal feed. Unfortunately, that important work was never completed. Since 1977, new research further demonstrates that adding antibiotics to livestock feed contributes to the growing problem of antibiotic resistance among food-borne and other pathogens. Those resistant bacteria can be transferred to humans via contaminated food products or through direct or indirect contact with animals.

While both agricultural and medical uses of antibiotics contribute to antibiotic resistance, sub- therapeutic use in animals is an important contributor to the problem.

I. **The FDA should ban sub-therapeutic uses of antibiotics in livestock of those antibiotics that may be used in (or that are related to those used in) human medicine**.

The ban should include sub-therapeutic uses of penicillin, tetracyclines, erythromycin, lincomycin, tylosin, virginiamycin, and other antibiotics used in human medicine or related to those used in human medicine for growth promotion and disease prevention. Sub-therapeutic use of those antibiotics in agriculture may jeopardize their effectiveness in treating human or animal diseases.

Banning sub-therapeutic agricultural antibiotic uses can lead to a decrease in antibiotic resistance among food-borne pathogens. For example, in Sweden, where glycopeptides have not been used as growth promoters since the early 1980s, and were formally banned in 1986, vancomycin- resistant enterococci are not found in isolates from pigs. In contrast, in the Netherlands, where glycopeptides only recently were banned, 39 percent of enterococci isolated from swine are vancomycin resistant.

II. **The sub-therapeutic use of antibiotics in livestock jeopardizes new human-use antibiotics and jeopardizes human health**.

A class of antibiotics called streptogramins is one of the last weapons against deadly antibiotic resistant bloodstream infections caused by antibiotic-resistant enterococci. Although it has not yet been approved for use in humans, the potential value of one streptogramin -- Synercid -- already has been compromised because of sub-therapeutic use of another antibiotic in the same class. That is because resistance to one antibiotic can cause resistance to the entire family of antibiotics. Turkeys that had been fed subtherapeutically another streptogramin, virginiamycin, harbor enterococci bacteria that also are resistant to Synercid. If people handle or consume turkey that is contaminated with those streptogramin-resistant enterococci and become ill, Synercid, if and when it is approved for human use, would be ineffective against that illness. In the U.S., Synercid-resistant bacteria have not yet been found in humans. However, in Germany, a country in which Synercid is not yet used in humans but in which virginiamycin is used subtherapeutically in livestock, Synercid-resistant enterococci have been detected in humans.

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III. **Leading health authorities around the world have called for banning subtherapeutic uses of certain antibiotics in agriculture.**

A number of authoritative organizations recognize that sub-therapeutic antibiotic use in livestock contributes to the development of antibiotic resistance and may pose a risk to human health.

The World Health Organization (WHO) recommends that the use of any antimicrobial for growth promotion in animals should be banned if it is (1) used in human therapeutics or (2) known to select for cross-resistance to antimicrobials used in human medicine.

The U.S. Centers for Disease Control and Prevention (CDC) has advised that the U.S. adopt the WHO position.

The National Academy of Sciences recently concluded that agricultural uses of antibiotics pose a risk to the public health.

In addition, most developed nations, with the notable exception of the United States and Canada, have banned the sub-therapeutic use of penicillin and tetracycline. Sweden has banned the use of any antibiotic. Denmark and Finland have banned several antibiotics for growth promotion. In December 1998, the European Union banned the use of four antibiotics used in animal feed because of concerns that those uses will undermine the effectiveness of antibiotics in human medicine (earlier it had banned other antibiotics).

I strongly urge you to take swift action to protect the effectiveness of antibiotics by limiting their subtherapeutic use in agriculture. Without such action, we jeopardize one of the great advancements in human and veterinary medicine.

Sincerely,

Douglas E. Morris
President